AMENDMENTS TO THE DRAWINGS:

Please insert the attached new drawing sheet into the file at the end of the specification.

REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS AND AMENDMENTS

Claims 1-5 were pending in this application when last examined and stand rejected.

Claims 2-5 have been cancelled without prejudice or disclaimer thereto. Applicant reserves the right to file a continuation or divisional application on any cancelled subject matter.

Claim 1 is amended to incorporate the subject matter of claims 2-5. Further support can be found at page 1, lines 20-24, page 2, lines 1-8, and the examples. Other minor editorial revisions have been made to claim 1 to better conform to U.S. claim form and practice. Such revisions are non-substantive and not intended to narrow the scope of protection. Such revisions include: replacing the "characterized" language with "wherein"; revising the claim language to provide proper antecedent basis for the recited terminology.

New claims 6-8 have been added. Support for the new claims can be found throughout the disclosure, for example, at page 1, lines 20-24, page 2, lines 1-8, and the examples and original claims 1-5.

No new matter has been added.

Claims 1 and 6-8 are pending upon entry of this amendment.

The specification has been amended to better conform to US practice for line spacing and use of trademarks and to correct typographical errors. Section headings and Brief Description of the Drawings were added as well. Applicant has also added a new drawing sheet for a illustrating one embodiment of the invention as supported by the disclosure, for example, at page 1, lines 20-24, page 2, lines 1-8, and the examples. The specification has been amended to include a Brief Description of the Drawing. Support can be found in the disclosure as filed. No new matter has been added by this amendment.

II. OBJECTIONS TO THE DRAWINGS AND THE SPECIFICATION

The drawing was objected for not including every feature of the invention specified in the claims for reasons stated in items 2-3 on pages 2-3 of the Office Action.

The specification was objected to for containing minor informalities with respect to line spacing and for improper use of a trademark. See in items 4-5 on page 3.

As noted above, a new drawing sheet is attached herewith, containing generic illustrations of the inhaler device. The attached drawing depicts a cross-section of the

device, including an inlet 10 for air intake, a body 12, including a permanent magnet 14 of strength above 1500 gauss and a mouthpiece 14. Using the mouthpiece, a patient draws air through the body and past the magnet, thereby inducing paramagnetism to oxygen in the air traveling through the device.

It is believed that this drawing depicts every feature specified in the claims, and thereby overcomes the noted objection to the drawing.

The specification was also objected for not spacing lines 1½ or using double spacing. The specification was also objected to for improper use of the trademark THERAHALER™. The present amendment overcomes these concerns by amending the specification, where appropriate, to correct the noted concerns.

In view of the above, the present amendment is believed to overcome the objections and withdrawal thereof is requested.

III. ENABLEMENT REJECTION

Claims 1-5 were rejected under 35 U.S.C. § 112 on the basis the specification lacks an enabling disclosure for the reasons stated in item 7 on page 4 of the Office Action. Specifically, it seems the Office is concerned with how with the electromagnetic field is generated in the device.

Applicant disagrees. Nonetheless, for the sole purpose of expediting prosecution and not to acquiesce to the rejection, Applicant has amended independent claim 1 and cancelled claims 2-5 to thereby address this rejection. Specifically, amended claim 1 no longer makes reference to "electromagnetic field", and instead specifies that the inhaler device contains "a permanent magnet having magnetic field above 1500 gauss".

New independent claim 6 corresponds to amended claim 1, but further characterizes the structural elements of the inhaler device.

It is believed that the specification enables the full scope of amended claim 1 and new claims 6-8. See, for instance, the disclosure at page 1, lines 20-24, page 2, lines 1-8, and the examples. The specification describes an inhaler device, including an inlet 10 for air intake, a body 12, including a permanent magnet 11 of strength above 1500 gauss and a mouthpiece 13. Using the mouthpiece, a patient draws air through the body and past the magnet, thereby inducing paramagnetism to oxygen in the air traveling through the device.

In view of the above, it is believed that the present amendment overcomes the enablement rejection and thus withdrawal therefore is requested.

IV. INDEFINITENESS REJECTION

Claims 1-5 were rejected under 35 U.S.C. § 112 as as being indefiniteness for the reasons stated in item 9 on pages 4-5 of the Office Action. This rejection is respectfully traversed.

It is respectfully submitted that the present amendment overcomes this rejection.

To start, claim 1 is amended to remove reference to electromagnetic field. Claim 1 is also amended to better specify the arrangement of the various elements of the claimed inhaler device. Claims 2-4 are cancelled. Such amendments obviate the concerns raised at the bottom of page 4 and the top of page 5 of the Action.

Further, it is believed that a detailed description, including the size or type of magnet, is not needed to satisfy the definiteness requirement. All that is needed is a permanent magnet having a magnetic field on the order of above 1500 gauss (a gauss being the basic unit of magnetic flux density for magnets) that is located in the stream of inhaled air traveling through the device. One of skill in the art would clearly understand and recognize the metes and bounds of this language, since such magnets are described in the disclosure and known to those with knowledge in the art.

In this regard, it is well established that definiteness of claim language is analyzed, not in a vacuum,

but in light of the knowledge in the art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. In re Moore, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971). See also, M.P.E.P., Eighth Ed., Rev. 6 (September 2007) at § 2173.02. Based on the knowledge in the art field, it is believed that a having a magnetic field on the order of above 1500 gauss is clear and definite to one skilled in the art.

Thus, withdrawal of the above rejections is requested.

V. PRIOR ART REJECTIONS

Claims 1-3 and 5 were rejected under 35 U.S.C. § 102(b) as being anticipated by Avrahami (US 6,328,033) for the reasons stated in item 11 on pages 5-6 of the Office Action.

Claim 4 was rejected under 35 U.S.C. § 103(a) as being obvious over Avrahami for the reasons stated in item 13 on pages 6-7.

These rejections are respectfully traversed as applied to amended claim 1 and new claims 6-8.

The anticipation rejection falls, because claim 1 is amended to incorporate the subject matter of claim 4, which was not included in the rejection. In fact, amended claim 1 and new claim 6 incorporate the subject matter of claims 2-5

(now cancelled). Claims 1 and claim 6 are the independent claims.

The obviousness rejection should fall, because: (1) Avrahami fails to disclose or suggest each and every element of independent claims 1 and 6; (2) it would not amount to routine optimization to modify the teachings in Avrahami to use a magnet having a magnetic field of at least 1500 gauss; and (3) the claimed inhaler achieves surprising and superior properties indicative of non-obviousness.

(1) Avrahami fails to disclose or suggest a magnet having magnetic field of at least 1500 gauss.

Amended claim 1 recites "permanent magnet having magnetic field above 1500 gauss between the inlet and the mouthpiece." Similarly, claim 6 recites: "a permanent magnet having magnetic field of at least 1500 gauss and positioned inside the body between the inlet and the mouthpiece" so that "the magnetic field induces paramagnetism to oxygen in said stream of air."

However, at the top of page 7, the Office acknowledges that the "Avrahami discloses all the limitations of claim 4 except the 1500-3000 gauss amount of magnetism in the magnetic field". It is again noted that dependent claim 4 has been incorporated into claims 1 and 6. Nonetheless, the Office asserts that this amount constitutes merely determining

optimum or workable ranges which only involves routine experimentation.

(2) Avrahami lacks a suggestion to modify its teachings to arrive at the claimed device, because it would not amount to routine optimization to modify the device in Avrahami to use a magnet having a magnetic field of at least 1500 gauss.

Applicants respectfully disagree with the Office's position that a person of ordinary skill in the art would reach the inhaler device according to claims 1 and 6 by routine optimization. As the Examiner is aware, a particular parameter or variable must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the parameter or variable might be characterized as routine or obvious. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980); See also M.P.E.P., Eighth Ed., Rev. 6 (September 2007) at § 2144.05, II, A, B.

However, no such recognition or suggestion of magnetic field strength above 1500 gauss is provided in the ground of rejection or in the cited reference of Avrahami. Indeed, Avrahami mentions nothing with respect to magnetic field strength measured in gauss, let alone one above 1500 gauss (in claims 1 and 6) to achieve paramagnetism (claim 6).

Thus, Avrahami does not recognize a magnetic field strength above 1500 gauss as being a result-effective variable to achieve a recognized result. For this reason, the routine optimization rationale fails and the obviousness rejection itself should fall.

Further, it should be noted that Avrahami discloses using the device disclosed therein for the administration of a dry powder. The magnetic field in the device is merely used to disaggregate the particles of the powder. See column 2, lines 13-20. This use of the magnet in Avrahami is completely different from that of claims 1 and 6, which desires paramagnetism of the oxygen in the air stream. The use in Avrahami is clearly not a suggestion that oxygen drawn into the inhaler is subject to paramagnetism. Indeed, Avrahami mentions nothing with respect to paramagnetism or the magnet's effect on the oxygen in the air. As such, the use of the magnet in the device Avrahami is clearly not suggestive nor predictive of a magnetic field strength of above 1500 gauss to achieve paramagnetism of the oxygen in the air. For this additional reason, it would not be obvious to optimize the magnetic field strength, since use magnets for a completely different purpose.

There is no basis in Avrahami nor a rationale provided in the Office Action to use a magnet having a

magnetic field strength of at least 1500 gauss to achieve paramagnetism of the oxygen.

For this reason, the obviousness rejection over Avrahami should fall.

(3) The claimed inhaler achieves surprising and superior properties indicative of non-obviousness.

As disclosed in detail at page 2 of the specification, experiments have shown that use of the claimed device leads to definite improvements to the immune system and that there have also been improvements in the enhancement of performance and well-being.

See, for instance, the results of Survey 2 and the observations thereof on pages 5-6 of the attached substitute specification, which disclose:

> 1. Players who use THERAHALER can expect to attain an extra 25% improvement in fitness levels after three weeks over player who do not use THERAHALER.
>
> 2. The greater percentage of THERAHALER players completing the three week course, held during a flu epidemic, would substantiate improve immune system function observed with the ASTHMATIC patient trial.
>
> 3. Players using THERAHALER reported an improved feeling of WELL BEING (as did ASTHMA patients) which indicates an improved confidence level and an improved all round state of health.
>
> 4. Tests using work load bicycle and measuring heart work & recovery rates yield supportive results, but in this rest, 25% placebos were used and they showed disappointing results.

These results are consistent with those reported in Surveys 3-5 on pages 6-13 of the disclosure.

For instance, the statistical results of Survey 3 show that the use of the claimed device improved the patient's quality of life as measured by the AQLQ(S) questionnaire.

Specifically, it showed that: (1) all patients report being able to breathe easier and can better perform their normal functions at work and home; (2) with one exception, all patients significantly reduced their medicine intake - two have stopped carrying their Bronchial dilator pumps around with them, and some have stopped using cortico steroids; (3) three patients got flu and one bronchitis after completing the test and reported no deterioration in their asthma, indicating that their immune system was functioning normally; (4) many patients can now enjoy foods, which they could not previously enjoy because it would trigger an asthma attack, again indicating that their immune systems have improved; (5) no adverse reactions or experiences were felt and all patients reported that they preferred using the claimed device because it is a non-medicated option utilizing natural principles; (6) improvement in peak flow meter readings indicated an improvement in lung function; (7) patients reported enjoying an uninterrupted nights sleep completing treatment, because wheezing and coughing had diminished or had ceased altogether.

Survey 4 shows that treatment with the claimed device improves blood oxygen levels without significantly disturbing blood CO_2 levels. See pages 12-13.

Survey 5 shows improvement in the immune system upon using the claimed device. Specifically, CD3 and CD4 counts show significant improvement during treatment with the claimed device. See page 13.

It is clear from these results that subjects who used the claimed inhaler device wherein the magnetic field was on the order of at least 1500 gauss and/or 1500 to 3000 gauss produced a remarkable result compared with those of the placebo group. This supports the position that the claimed inhaler device achieves surprising and unexpected results.

This is further evidence as to the nonobviousness of the claimed inhaler device.

In summary, it is believed that the rejection falls, because (1) Avrahami fails to disclose or suggest each and every element of independent claims 1 and 6; (2) it would not amount to routine optimization to modify the teachings in Avrahami to arrive at the claimed device; and (3) the claimed inhaler achieves surprising and superior properties indicative of non-obviousness.

Thus, claims 1 and 6 and all claims dependent thereon are novel and patentable over Avrahami. Therefore, the

obviousness rejection over Avrahami is untenable and should be withdrawn.

Further, Applicants respectfully submit that the references cited but not relied upon (Opitz (US 7,100,605), Arnott (US 6,763,828), and Egin (SU 1597195A1) in item 14 on page 7 of the Action also do not render obvious the claimed inhaler device. These references cited by the Examiner and the EPO pertain to use of magnetic fields to assist in the action of medicaments being inhaled.

However, none relate to the use of a magnet having a magnetic field strength of at least 1500 gauss using only the oxygen in air. In this regard, Opitz does not disclose a magnet. Arnott uses magnets to cause the piston to move and drive a bolus of air, and not to cause paramagnetism to the air. SU 1597195 involves use of an inhalant composition and magnet, and not to a magnetic field strength of at least 1500 gauss causing paramagnetism to the oxygen in air. For these reasons, these references do not render obvious the claims.

VII. CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested. If the Examiner has any comments or

proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following item(s):

☒ - a New drawing sheet for Figure

☒ - a Substitute Specification both clean copy and a marked-up copy of the originally-filed specification